

MAY 28 2009

K090602

pg. 1 of 3

Section 5 – Premarket Notification 510(k) Summary

GENERAL INFORMATION:

Device Name and Classification

Product Name: BioZ Rx Hemodynamic Monitor with 12-Lead ECG
Classification Name: Plethysmography, Impedance
Common Name: Impedance Cardiograph (ICG)
Classification Panel: Cardiovascular
Regulation Number: 21 CFR 870.2770 (for ICG) and 21 CFR 870.2340 (for ECG)
Device Class: II
Product Code: 74 DSB (for ICG) and 74 DPS (for ECG)

Manufacturer and Contact Person

CardioDynamics International Corporation
6175 Nancy Ridge Drive, # 300
San Diego, CA 92121 USA
Phone: 858-535-0202 x1028
Fax: 866-581-9123

Donald J. Brooks
Chief Technology Officer

Date of Summary Preparation: February 27, 2009

SUBSTANTIAL EQUIVALENCE:

Predicate Devices:

K070156 – CardioDynamics BioZ® Dx Hemodynamic Monitor with 12-Lead ECG
K051228 – CardioDynamics BioZ® Dx Hemodynamic Monitor and Philips 12-Lead ECG
K052158 – Welch/Allyn Cardioperfect Software with Accessories
K962854 – Welch/Allyn Cardioperfect Portable

Device Description:

This submission for the BioZ Rx covers a PC platform/printer/cart change and user software modifications compared to the predicate BioZ Dx System (K070156 and K051228), which is a noninvasive impedance cardiography (ICG) device that provides hemodynamic parameters based on the measurement of thoracic electrical bioimpedance. The BioZ Rx measures this change in impedance by injecting a high frequency, low amplitude alternating electrical current through the thorax between a pair of sensors placed on the neck and another pair placed on the mid-axillary line at the xiphoid process level. By detecting and measuring the change in thoracic impedance as a function of time, the BioZ Rx is able to calculate stroke volume, cardiac output and many other hemodynamic parameters.

The device additionally includes the capability of performing a standard 12-Lead ECG test using previously cleared Welch/Allyn software and USB patient interface accessories (K052158 and K962854).

All ICG signal processing and parameter measurements and calculations are identical to predicate device. Those tasks are performed within the ICG Patient Interface Module (PIM) which is essentially unchanged from the predicate device.

Intended Use:

The BioZ Rx device has the same intended uses as the predicate BioZ Dx device which was intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The devices are intended to monitor hemodynamic parameters within hospitals and other healthcare facilities providing patient care.

The Optional 12-Lead ECG Function of the BioX Rx device is indicated for use where the physician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

Technology:

The BioZ Rx device has the identical ICG Patient Interface Module as the predicate BioZ Dx device, with the exception of:

- A small change made to the USB communication processor in the PIM to enable and service the watchdog timer to facilitate automatic reconnection and restoration of monitoring in the event of a communication interruption between the PIM and the CPU.
- Some other additional small changes made to facilitate communication with the faster CPU platform.

The communication processor is not involved in the acquisition and processing of patient hemodynamic data.

The computer platform for the user interface has been changed from the ARM-PC-based Philips PageWriter Trim platform to a self-contained PC and touch-screen monitor manufactured by Advantech, and an off the shelf inkjet printer. Numerous human factors improvements has been made to the user software, facilitated by the significantly larger touch-screen interface of the new platform. The ECG Patient Interface Module has been replaced by an equivalent device (also USB-based) and software from Welch/Allyn, Inc., previously cleared under K052158 and K962854.

General Safety & Effectiveness Concerns:

The instructions for use for this device contain the necessary cautions and warnings to provide for safe and effective use for the device.

Risk management is an essential element of the design and development process, and hazard analysis assessments performed on the BioZ Rx device at the System and Software levels revealed that the enhancements present no additional risks from the predicate devices. The Software and System Hazard Analyses for the modified device are included in Section 18.

Manufacturing:

CardioDynamics International Corporation is presently certified to ISO13485 2003 as of 2/17/09 by NEMKO AS. No significant audit findings have been presented since initial ISO 9004 (now 13485) certification in May of 1998. All products are designed and manufactured under CDIC's Quality Management System, which includes Design Control and Good Manufacturing Practices.

Performance Testing:

There have been no hardware, cable, or signal processing modifications in the patient interface portion of the BioZ Rx compared to the predicate BioZ Dx monitor device. The ICG changes are limited to the computer platform for the user interface and the use of an off-the-shelf printer.

The Optional 12-lead ECG function uses a USB-based ECG Patient Interface Module like the predicate device. The supplier has been changed from Philips to Welch/Allyn. Both the predicate device and the ECG device and software of the BioZ Rx are tested and certified to comply with the relevant recognized consensus standards, including EN60601-1, EN60601-1-1, and EN60601-1-25. The issued Certificates of Conformity to these standards are included in Section 9. We are awaiting final agency processing on the CB Scheme report at the system level. Testing of the Welch/Allyn patient interface and software at the system level is included in the testing documented in Section 18. The new user interface platform, including the cart, printer, ICG and ECG interface modules and all cables have been tested by NEMKO and TUV for electrical safety, electromagnetic emissions, and electromagnetic immunity to the appropriate International consensus standards. The test reports are included in Section 18 and the Certificates of Conformity are included in Section 9.

Design Controls

Design Review is required, at a minimum, at the completion of each step in the design control process (i.e. Design Input, Design Output, Design Verification, Design Validation and Design Transfer). The design review process identifies the required deliverables for each step in the process and verifies the content and accuracy of each deliverable.

The following quality assurance measures were conducted for the modified BioZ Rx device and are included in this submission:

- Risk analysis
- Design requirements and traceability
- Unit and system level software and firmware verifications
- System level validations

The results of verification and validation tests concluded that the functionality and performance characteristics of the modified BioZ Dx are comparable to the currently marketed predicate devices.

Conclusion:

The results of all testing demonstrate that the BioZ Rx Hemodynamic Monitor with Optional 12-Lead ECG does not raise any new significant issues of safety, effectiveness or performance of the device when compare to the existing predicate devices.



MAY 28 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardiodynamics International Corporation
C/O Mr. Don Brooks
6175 Nancy Ridge Drive, #300
San Diego, CA 92121

Re: K090602

Trade/Device Name: BioZ Rx HemoDynamic Monitor with Optional 12-lead ECG
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Codes: DSB
Dated: February 27, 2009
Received: March 5, 2009

Dear Mr. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

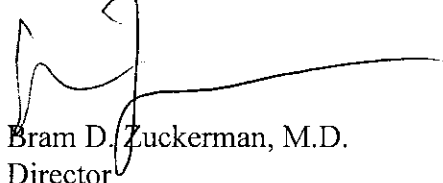
Page 2 – Mr. Don Brooks

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090602

Device Name: BioZ Rx HemoDynamic Monitor with Optional 12-lead ECG

Indications For Use:

For the ICG function:

The BioZ Rx Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

Heart Rate (HR)	Thoracic Fluid Content Index (TFCI)
Systolic Blood Pressure (SBP)	Systolic Time Ratio (STR)
Diastolic Blood Pressure (DBP)	Systolic Time Ratio Index (STRI)
Mean Arterial Blood Pressure (MAP)	Pre-Ejection Period (PEP)
Stroke Index (SI)	Left Ventricular Ejection Time (LVET)
Stroke Volume (SV)	Total Arterial Compliance (TAC)
Cardiac Index (CI)	Total Arterial Compliance Index (TACI)
Cardiac Output (CO)	Left Stroke Work Index (LSWI)
Systemic Vascular Resistance (SVR)	Heather Index (HI)
Systemic Vascular Resistance Index (SVRI)	Q-C Interval (QC)
Left Cardiac Work (LCW)	Left Cardiac Work Index (LCWI)
Acceleration Index (ACI)	Systemic Stroke Resistance Index (SSRI/SSVRI)
Velocity Index/Index of Contractility (VI, IC)	Base Impedance (TFI or Z_0)
Thoracic Fluid Content (TFC)	Electrocardiogram (ECG)

For the optional 12-lead ECG function:

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090602